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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,626	03/30/2006	Jennifer Ruth Gamble	650063.402USPC	8192

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EXAMINER	
SGAGIAS, MAGDALENE K	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/531,626	GAMBLE ET AL.	
	Examiner	Art Unit	
	Magdalene K. Sgagias	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/30/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

Group I, claims 1, 2, 4-14, 20, 26, 27 and 29-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a nucleic acid encoding sphingosine kinase and use of a nucleic acid encoding sphingosine kinase for modulating the functional level of sphingosine kinase.

Group II, claims 1, 2, 4-14, 20, 26, 27 and 29-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing sphingosine kinase and use of sphingosine kinase for modulating the functional level of sphingosine kinase and use of sphingosine kinase.

Group III, claims 1, 2, 4-14, 20, 26, 27 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by a sphingosine kinase mimetic.

Group IV, claims 1, 2, 4-14, 21, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene and a use of a

proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene.

Group V, claims 1, 2, 4-14, 21, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a non-proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene and a use of a non-proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene.

Group VI, claims 1, 2, 4-14, 22, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a proteinaceous agonist of sphingosine and a use of a proteinaceous agonist.

Group VII, claims 1, 2, 4-14, 22, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a non-proteinaceous agonist of sphingosine and a use of a non-proteinaceous agonist.

Group VIII, claims 1, 2, 4-14, 23, 24, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a proteinaceous antagonist of sphingosine and a use of a proteinaceous agonist.

Group IX, claims 1, 2, 4-14, 23, 24, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a non-proteinaceous antagonist of sphingosine and a use of a non-proteinaceous agonist.

Group X, claims 1-20, 25, 27, 29-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing a nucleic acid encoding sphingosine kinase and use of a nucleic acid encoding sphingosine kinase for modulating the functional level of sphingosine kinase.

Group XI, claims 1-20, 25, 27, 29-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing sphingosine kinase and use of sphingosine kinase for modulating the functional level of sphingosine kinase and use of sphingosine kinase.

Group XII, claims 1, 2, 4-14, 20, 25, 27, 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by a sphingosine kinase mimetic.

Group XIII, claims 1-19, 21, 25, 27, 28, 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing a proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene and a use of a

proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene.

Group XIV, claims 1-19, 21, 25, 27, 28, 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing a non-proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene and a use of a non-proteinaceous molecule which modulates transcriptional and/or translational regulation of the sphingosine kinase gene.

Group XV, claims 1-19, 22, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing a proteinaceous agonist of sphingosine and a use of a proteinaceous agonist.

Group XVI, claims 1-19, 22, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing a non-proteinaceous agonist of sphingosine and a use of a non-proteinaceous agonist.

Group XVII, claims 1-19, 23, 24, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing a proteinaceous antagonist of sphingosine and a use of a proteinaceous agonist.

Group XVIII, claims 1-19, 23, 24, 26-28 and 30-43, drawn to a method of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vivo the functional level of sphingosine kinase by introducing a non-proteinaceous antagonist of sphingosine and a use of a non-proteinaceous agonist.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of groups I-XVIII are distinct from each other because they are drawn to methods that have distinct steps, require separate compositions for practice and produce different product or results. For example, the steps of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro the functional level of sphingosine kinase by introducing a nucleic acid encoding sphingosine kinase and use of a nucleic acid encoding sphingosine kinase for modulating the functional level of sphingosine kinase, of group I cannot be used in introducing sphingosine kinase and use of sphingosine kinase for modulating the functional level of sphingosine kinase and use of sphingosine kinase of group II. Similarly the steps of modulating one or more mammalian endothelial cell functional characteristics comprising modulating in vitro of groups I-IX cannot be used in vivo for groups X-XVIII. An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See 37 C.F.R 1.475 (a). If multiple products,

processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R 1.475 (d) and 37 C.F.R 1.476 (c). Accordingly, Groups I-XVIII are not linked by a special technical feature.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla, can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630